

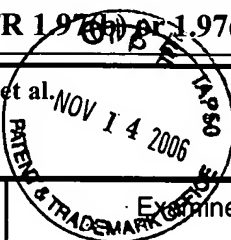
TRW

<b>TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT</b> (Under 37 CFR 1.97(b) or 1.97(c))				Docket No. 17530	
In Re: Application Of <b>Robert James, et al.</b>					
Application No. 10/800,322	Filing Date March 12, 2004	Examiner Jennifer Shin Shin Wong	Customer No. 23389	Group Art Unit 1634	Confirmation No. 2289
Title: <b>NUCLEIC ACID MARKERS FOR USE IN DETERMINING PREDISPOSITION TO NEOPLASM AND/OR ADENOMA</b>					
Address to: <b>Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450</b>					
<b>37 CFR 1.97(b)</b>					
1. <input checked="" type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.					
<b>37 CFR 1.97(c)</b>					
2. <input type="checkbox"/> The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:					
<input type="checkbox"/> the statement specified in 37 CFR 1.97(e);					
<b>OR</b>					
<input type="checkbox"/> the fee set forth in 37 CFR 1.17(p).					

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
17530

In Re Application of: Robert James, et al.



Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/800,322	March 12, 2004	Jennifer Shin Shin Wong	23389	1634	2289

Title:

**NUCLEIC ACID MARKERS FOR USE IN DETERMINING PREDISPOSITION TO NEOPLASM AND/OR ADENOMA**

**Payment of Fee**

(Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))

- ☐ A check in the amount of \_\_\_\_\_ is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. 19-1013/SSMP as described below.
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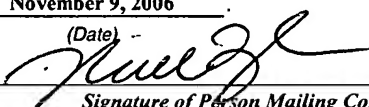
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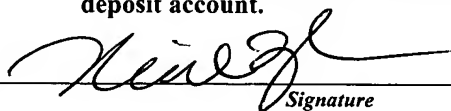
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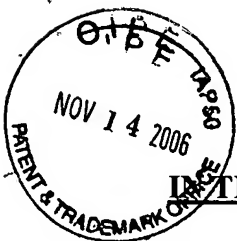
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Dated: November 9, 2006

Xiaochun Zhu  
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516-742-4343

CC:



**THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Applicants:** Robert James, et al.. **Examiner:** Jennifer Shin Shin Wong  
**Serial No.:** 10/800,322 **Art Unit:** 1634  
**Filed:** March 12, 2004 **Docket:** 17530  
**For:** NUCLEIC ACID MARKERS FOR USE **Dated:** November 9, 2006  
IN DETERMINING PREDISPOSITION TO  
NEOPLASM AND/OR ADENOMA

**Confirmation No.:** 2289

Mail Stop Amendment  
Commissioner for Patents  
P. O. Box 1450  
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**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R §§1.97 and 1.98, it is requested that the following references, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. GenBank Accession No. AC012324.7, *Homo sapiens* chromosome 16 clone RP11-92P14 (2001);
2. GenBank Accession No. AC079240.6, *Homo sapiens* chromosome 4 clone RP11-808H17 (2001), Waterston R.H.;
3. GenBank Accession No. AC004024.2, *Homo sapiens* 12q24.2 PAC RPCI1-128M12 (2000), Muzny D. et al.;

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

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Dated: November 9, 2006

  
Xiaochun Zhu

4. GenBank Accession No. AF117829.1, *Homo sapiens* 8q21:3: RICK gene (1999), Platzer M. et al.;
5. GenBank Accession No. AC004459.1, *Homo sapiens* BAC clone CTA-273G1 from 8q21 (2000), Bradshaw H. et al.;
6. GenBank Accession No. AC023302.5, *Homo sapiens* clone RP11-28H5 (2001), Birren B. et al.;
7. GenBank Accession No. AL138715.11, Human DNA sequence from clone RP11-77P19 on chromosome 13 (2000), Blakey S.;
8. GenBank Accession No. AP000542.1, *Homo sapiens* genomic DNA, chromosome 22q11.2, Cat eye syndrome region (2000), Shimizu N.;
9. GenBank Accession No. AC023150.5, *Homo sapiens* chromosome 4 clone RP11-709L9 (2001), Waterston R.H.;
10. GenBank Accession No. AC008381.8, *Homo sapiens* chromosome 5 clone CTC-216O13 (2001);
11. GenBank Accession No. AF345934.1, *Homo sapiens* regenerating gene type IV mRNA (2001), Violette S. et al.;
12. Hartupée J.C. et al., "Isolation and Characterization of a cDNA Encoding a Novel Member of the Human Regenerating Protein Family: Reg IV<sup>1</sup>", *Biochimica et Biophysica Acta* 1518(3):287-293 (2001);
13. GenBank Accession No. NM\_032044.1, *Homo sapiens* regenerating gene type IV (REG-IV) (2001), Hartupée J.C. et al.;
14. Shinozaki S. et al., "Upregulation of Reg 1 $\alpha$  and GW112 in the Epithelium of Inflamed Colonic Mucosa", *Gut* 48(5):623-629 (2001);
15. GenBank Accession No. NM\_006418.2, *Homo sapiens* differentially expressed in hematopoietic lineages (GW112) (2001), Shinozaki S. et al.;
16. GenBank Accession No. NM\_001046.1, *Homo sapiens* solute carrier family 12 (sodium/potassium/chloride transporters), member 2 (SLC12A2) (2000), Payne J.A. et al.;
17. Payne J.A. et al., "Primary Structure, Functional Expression, and Chromosomal Localization of the Bumetanide-Sensitive Na-K-Cl Contranporter in Human Colon", *The Journal of Biological Chemistry* 270(30):17977-17985 (1995);

18. GenBank Accession No. AC007860.6, *Homo sapiens* 12p13 BAC RPC11-709E21 (1999), Muzny D. et al.;
19. GenBank Accession No. AC012519.9, *Homo sapiens* 3 BAC RP11-1036F1 (2000), Muzny D. et al.;
20. GenBank Accession No. AJ238592.1, *Homo sapiens* SLAP gene promoter region (1999), Witter K. et al.;
21. GenBank Accession No. AF235100.3, *Homo sapiens* chromosome 8 map 8q24.3 PAC RP6-98A24 containing part of the thyroglobulin (TG) gene and part of the gene for Src-like adapter protein (2000), Blechschmidt K. et al.;
22. GenBank Accession No. AC004687.1, *Homo sapiens* chromosome 17, clone hRPC.1171\_I\_10 (1998), Virren B. et al.;
23. GenBank Accession No. AL049766.14, Human DNA sequence from clone RP4-686N3 on chromosome 20q13.2-13. Contains the 3' part of the gene for a novel ATP dependent RNA helicase (contains conserved C-terminal helicase domains and DEAD/DEAH boxes), the KIAA1404 gene (2001), Corby N.;
24. GenBank Accession No. AP000866.4, *Homo sapiens* genomic DNA, chromosome 11q, clone:RP11-677M14 (2001), Hattori M. et al.;
25. GenBank Accession No. AK022999.1, *Homo sapiens* cDNA FLJ12937 fis, clone NT2RP2005020 (2000), Isogai T. et al.;
26. GenBank Accession No. AL050021.1, *Homo sapiens* mRNA, cDNA DKFZp564D016 (from clone DKFZp564D016) (2000), Wambutt R. et al.;
27. GenBank Accession No. AK023154.1, *Homo sapiens* cDNA FLJ13092 fis, clone NT2RP3002147 (2000), Isogai T. et al.;
28. EMBL Accession No. AC013410.5, *Homo sapiens* BAC clone RP11-495I2 from 2 (2001), Edwards J. et al.;
29. EMBL Accession No. AL445248.7, Human DNA sequence from clone RP11-277A4 on chromosome 1 (2000), Cobley V.;
30. EMBL Accession No. AL078591.18, Human DNA sequence from clone RP1-198I9 on chromosome 6q12-13. Contains the gene KIAA1411 (2000), Babbage A.;
31. EMBL Accession No. L13616.1, Human focal adhesion kinase (FAK) mRNA (1994), Whitney G.S. et al.;

32. Whitney G.S. et al., "Human T and B Lymphocytes Express a Structurally Conserved Focal Adhesion Kinase pp125FAK", *DNA and Cell Biology* 12(9):823-830 (1993);
33. Tommerup N. et al., "Isolation and Fine Mapping of 16 Novel Human Zinc Finger-Encoding cDNAs Identify Putative Candidate Genes for Developmental and Malignant Disorders", *Genomics* 27(2):259-264 (1995);
34. EMBL Accession No. U09848.1, Human zinc finger protein (NF139) mRNA (1995), Tommerup N. et al.;
35. Zendman A.J.W. et al., "TM7XN1, a Novel Human EGF-TM7-Like cDNA, Detected with mRNA Differential Display Using Human Melanoma Cell Lines with Different Metastatic Potential", *FEBS Letter* 446(2-3):292-298 (1999);
36. GenBank Accession No. AJ011001.1, *Homo sapiens* mRNA for TM7XN1 protein (1999), Zendman A.J. et al.;
37. EMBL Accession No. AK025080.1, *Homo sapiens* cDNA: FLJ21427 fis, clone COL04177 (2000), Sugano S. et al.;
38. EMBL Accession No. AK025039.1, *Homo sapiens* cDNA: FLJ21386 fis, clone COL03414 (2000), Sugano S. et al.;
39. GenBank Accession No. XM\_015882.1, *Homo sapiens* hypothetical protein FLJ22792 (FLJ22792) (2001);
40. EMBL Accession No. Z99943.1, Human DNA sequence from PAC 313L4 on chromosome 1q24 (1999), Pearce A.;
41. EMBL Accession No. AK024700.1, *Homo sapiens* cDNA: FLJ21047 fis, clone CAS00253 (2000), Sugano S. et al.;
42. GenBank Accession No. NM\_001675.1, *Homo sapiens* activating transcription factor 4 (tax-responsive enhancer element B67) (ATF4) (2000), Tsujimoto A. et al.;
43. Tsujimoto A. et al., "Isolation of cDNAs for DNA-Binding Proteins Which Specifically Bind to a Tax-Responsive Enhancer Element in the Long Terminal Repeat of Human T-Cell Leukemia Virus Type I", *Journal of Virology* 65(3):1420-1426 (1991);
44. Karpinski B.A. et al., "Molecular Cloning of Human CREB-2: An ATF/CREB Transcription Factor that Can Negatively Regulate Transcription from the

cAMP Response Element”, *Proceedings of the National Academy of Sciences USA* 89:4820-4824 (1992);

45. EMBL Accession NO. AC022489.7, *Homo sapiens* chromosome 4 clone RP11-671P3 from 4, (2001), Waterston R.H.;
46. GenBank Accession No. AL356738.4, *Homo sapiens* chromosome X clone RP13-228I21, (2001), Mclay K.;
47. GenBank Accession No. AC005829.1, *Homo sapiens* chromosome 17, clone hRPK.259\_G\_18 (1998), Birren B. et al.;
48. Bast, Jr. R.C. et al., “2000 Update of Recommendations for the Use of Tumor Markers in Breast and Colorectal Cancer: Clinical Practice Guidelines of the American Society of Clinical Oncology”, *Journal of Clinical Oncology* 19(6):1865-1878 (2001);
49. Van Laethem J.L., “Use of Genetic Markers During Endoscopic Screening and Follow-Up of Gastrointestinal Precancerous Lesions”, *Acta Gastro-Enterologica Belgica* 58(2):187-192 (1995); and
50. United States Patent No. 5,702,886, dated December 30, 1997 to Vogelstein et al.

The references were cited in an International Search Report dated February 19, 2003 received from the Australian Patent Office. Applicants are submitting copies of Reference Nos. 1-49, together with a copy of the International Search Report. In accordance with the waiver of 37 C.F.R. 1.98 (a)(2)(i) in effect as of June 30, 2003, Applicants are not required to submit a copy of the above-cited U.S. Patent reference. The relevance of the above-identified references has been described in the International Search Report.

Inasmuch as this Information Disclosure Statement is being submitted in accordance with the schedule set out in 37 C.F.R. § 1.97(b), no statement or fee is required.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Xiaochun Zhu', written in a cursive style.

Xiaochun Zhu

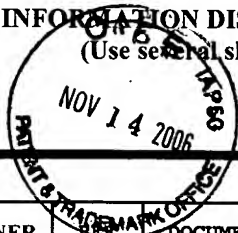
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Scully, Scott, Murphy & Presser, P.C.  
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Garden City, New York 11530  
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XZ:dg



**INFORMATION DISCLOSURE CITATION**  
(Use several sheets if necessary)



Docket Number (Optional)  
**17530**

Application Number  
**10/800,322**

Applicant(s)  
**Robert James, et al.**

Filing Date  
**March 12, 2004**

Group Art Unit  
**1634**

**U.S. PATENT DOCUMENTS**

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5,702,886	12/30/97	Vogelstein et al.			

**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	GenBank Accession No. AC012324.7, <i>Homo sapiens</i> chromosome 16 clone RP11-92P14 (2001)
	GenBank Accession No. AC079240.6, <i>Homo sapiens</i> chromosome 4 clone RP11-808H17 (2001), Waterston R.H.
	GenBank Accession No. AC004024.2, <i>Homo sapiens</i> 12q24.2 PAC RPC11-128M12 (2000), Muzny D. et al.
	GenBank Accession No. AF117829.1, <i>Homo sapiens</i> 8q21:3: RICK gene (1999), Platzer M. et al.
	GenBank Accession No. AC004459.1, <i>Homo sapiens</i> BAC clone CTA-273G1 from 8q21 (2000), Bradshaw H. et al.
	GenBank Accession No. AC023302.5, <i>Homo sapiens</i> clone RP11-28H5 (2001), Birren B. et al.
	GenBank Accession No. AL138715.11, Human DNA sequence from clone RP11-77P19 on chromosome 13 (2000), Blakey S.
	GenBank Accession No. AP000542.1, <i>Homo sapiens</i> genomic DNA, chromosome 22q11.2, Cat eye syndrome region (2000), Shimizu N.
	GenBank Accession No. AC023150.5, <i>Homo sapiens</i> chromosome 4 clone RP11-709L9 (2001), Waterston R.H.
	GenBank Accession No. AC008381.8, <i>Homo sapiens</i> chromosome 5 clone CTC-216O13 (2001)

**EXAMINER**

**DATE CONSIDERED**

**EXAMINER:** Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<b>INFORMATION DISCLOSURE CITATION</b> (Use several sheets if necessary)		Docket Number (Optional) <b>17530</b>	Application Number <b>10/800,322</b>
		Applicant(s) <b>Robert James, et al.</b>	
		Filing Date <b>March 12, 2004</b>	Group Art Unit <b>1634</b>
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		GenBank Accession No. AF345934.1, <i>Homo sapiens</i> regenerating gene type IV mRNA (2001), Violette S. et al.	
		Hartupée J.C. et al., "Isolation and Characterization of a cDNA Encoding a Novel Member of the Human Regenerating Protein Family: Reg IV <sup>1</sup> ", <i>Biochimica et Biophysica Acta</i> 1518(3):287-293 (2001)	
		GenBank Accession No. NM_032044.1, <i>Homo sapiens</i> regenerating gene type IV (REG-IV) (2001), Hartupée J.C. et al.	
		Shinozaki S. et al., "Upregulation of Reg 1α and GW112 in the Epithelium of Inflamed Colonic Mucosa", <i>Gut</i> 48(5):623-629 (2001)	
		GenBank Accession No. NM_006418.2, <i>Homo sapiens</i> differentially expressed in hematopoietic lineages (GW112) (2001), Shinozaki S. et al.	
		GenBank Accession No. NM_001046.1, <i>Homo sapiens</i> solute carrier family 12 (sodium/potassium/chloride transporters), member 2 (SLC12A2) (2000), Payne J.A. et al.	
		Payne J.A. et al., "Primary Structure, Functional Expression, and Chromosomal Localization of the Bumetanide-Sensitive Na-K-Cl Cotransporter in Human Colon", <i>The Journal of Biological Chemistry</i> 270(30):17977-17985 (1995)	
		GenBank Accession No. AC007860.6, <i>Homo sapiens</i> 12p13 BAC RPC11-709E21 (1999), Muzny D. et al.	
		GenBank Accession No. AC012519.9, <i>Homo sapiens</i> 3 BAC RP11-1036F1 (2000), Muzny D. et al.	
		GenBank Accession No. AJ238592.1, <i>Homo sapiens</i> SLAP gene promoter region (1999), Witter K. et al.	
		GenBank Accession No. AF235100.3, <i>Homo sapiens</i> chromosome 8 map 8q24.3 PAC RP6-98A24 containing part of the thyroglobulin (TG) gene and part of the gene for Src-like adapter protein (2000), Blechschmidt K. et al.	
		GenBank Accession No. AC004687.1, <i>Homo sapiens</i> chromosome 17, clone hRPC.1171_I_10 (1998), Virren B. et al.	
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		GenBank Accession No. AL049766.14, Human DNA sequence from clone RP4-686N3 on chromosome 20q13.2-13. Contains the 3' part of the gene for a novel ATP dependent RNA helicase (contains conserved C-terminal helicase domains and DEAD/DEAH boxes), the KIAA1404 gene (2001), Corby N.	
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		EMBL Accession No. AL078591.18, Human DNA sequence from clone RP1-198I9 on chromosome 6q12-13. Contains the gene KIAA1411 (2000), Babbage A.	
		EMBL Accession No. L13616.1, Human focal adhesion kinase (FAK) mRNA (1994), Whitney G.S. et al.	
		Whitney G.S. et al., "Human T and B Lymphocytes Express a Structurally Conserved Focal Adhesion Kinase pp125FAK", <i>DNA and Cell Biology</i> 12(9):823-830 (1993)	
		Tommerup N. et al., "Isolation and Fine Mapping of 16 Novel Human Zinc Finger-Encoding cDNAs Identify Putative Candidate Genes for Developmental and Malignant Disorders", <i>Genomics</i> 27(2):259-264 (1995)	
		EMBL Accession No. U09848.1, Human zinc finger protein (NF139) mRNA (1995), Tommerup N. et al.	
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

		Zendman A.J.W. et al., "TM7XN1, a Novel Human EGF-TM7-Like cDNA, Detected with mRNA Differential Display Using Human Melanoma Cell Lines with Different Metastatic Potential", <i>FEBS Letter</i> 446(2-3):292-298 (1999)
		GenBank Accession No. AJ011001.1, <i>Homo sapiens</i> mRNA for TM7XN1 protein (1999), Zendman A.J. et al.
		EMBL Accession No. AK025080.1, <i>Homo sapiens</i> cDNA: FLJ21427 fis, clone COL04177 (2000), Sugano S. et al.
		EMBL Accession No. AK025039.1, <i>Homo sapiens</i> cDNA: FLJ21386 fis, clone COL03414 (2000), Sugano S. et al.
		GenBank Accession No. XM_015882.1, <i>Homo sapiens</i> hypothetical protein FLJ22792 (FLJ22792) (2001)
		EMBL Accession No. Z99943.1, Human DNA sequence from PAC 313L4 on chromosome 1q24 (1999), Pearce A.
		EMBL Accession No. AK024700.1, <i>Homo sapiens</i> cDNA: FLJ21047 fis, clone CAS00253 (2000), Sugano S. et al.
		GenBank Accession No. NM_001675.1, <i>Homo sapiens</i> activating transcription factor 4 (tax-responsive enhancer element B67) (ATF4) (2000), Tsujimoto A. et al.
		Tsujimoto A. et al., "Isolation of cDNAs for DNA-Binding Proteins Which Specifically Bind to a Tax-Responsive Enhancer Element in the Long Terminal Repeat of Human T-Cell Leukemia Virus Type I", <i>Journal of Virology</i> 65(3):1420-1426 (1991)
		Karpinski B.A. et al., "Molecular Cloning of Human CREB-2: An ATF/CREB Transcription Factor that Can Negatively Regulate Transcription from the cAMP Response Element", <i>Proceedings of the National Academy of Sciences USA</i> 89:4820-4824 (1992)
		EMBL Accession NO. AC022489.7, <i>Homo sapiens</i> chromosome 4 clone RP11-671P3 from 4, (2001), Waterston R.H.
		GenBank Accession No. AL356738.4, <i>Homo sapiens</i> chromosome X clone RP13-228I21, (2001), Mclay K.

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<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
		GenBank Accession No. AC005829.1, <i>Homo sapiens</i> chromosome 17, clone hRPK.259_G_18 (1998), Birren B. et al.	
		Bast, Jr. R.C. et al., "2000 Update of Recommendations for the Use of Tumor Markers in Breast and Colorectal Cancer: Clinical Practice Guidelines of the American Society of Clinical Oncology", <i>Journal of Clinical Oncology</i> 19(6):1865-1878 (2001)	
		Van Laethem J.L., "Use of Genetic Markers During Endoscopic Screening and Follow-Up of Gastrointestinal Precancerous Lesions", <i>Acta Gastro-Enterologica Belgica</i> 58(2):187-192 (1995)	
EXAMINER		DATE CONSIDERED	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			